

SAFETY DATA SHEET

RSDL® (Reactive Skin Decontamination Lotion Kit)

PRODUCT CODE: 1900733

This Safety Data Sheet contains information concerning the potential risks to those involved in handling, transporting and working with the material, as well as describing potential risks to the consumer and the environment. This information must be made available to those who may come into contact with the material or are responsible for the use of the material. This Safety Data Sheet is prepared in accordance with formatting described in the REACH Regulation (EC) No 1907/2006, and described in CLP Regulation (EC) No 1272/2008.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name: RSDL® (Reactive Skin Decontamination Lotion Kit)

Product Code: 1900733

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified use: RSDL (Reactive Skin Decontamination Lotion Kit) has been cleared by the United States Food and Drug Administration as a medical device for the decontamination of skin exposed to chemical warfare agents and T-2 toxin.

Uses advised against: Any uses other than its intended use as a medical device for the decontamination of skin exposed to chemical warfare agents and T-2 toxin. Product should only be used in accordance with the manufacturer label.

1.3 Details of the supplier of the safety data sheet

Emergent Protective Products USA Inc.

46 Shelby Thames Drive

Hattiesburg, MS 39402

United States of America

Tel: 1-888-773-3266

E mail: CustomerService@ebsi.com

1.4 Emergency telephone number

In case of emergency Tel. Within the U.S.: 800-535-5053

Tel. In the EU: +44 2083348527

SECTION 2: Hazards Identification

2.1 Classification of the mixture

Classification in accordance with the Classification Labelling and Packaging Regulation EC (no) 1272/2008

NONE

Classification in accordance with the Dangerous Substances Directive 67/548/EEC/Dangerous Preparations Directive 1999/EC

NONE

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008

Pictogram

NONE

Signal word

NONE

Hazard statements

NONE

Precautionary statements

P280

2.3 Other hazards

This mixture contains no components considered to be either persistent, bioaccumulative or toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition

3.1 Mixtures

Name	CAS or EC No, Registration No* (if available)	Concentration	Classification DSD 67/548/EEC CLP 1272/2008
RSDL	NA	100%	
Methoxy polyethylene Glycol 550	CAS 9004-74-4 EC	60 – 100%	Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008. This substance is not classified as dangerous according to Directive 67/548/EEC.
KBDO	CAS 103411-45-6	10 – 30%	
DAM (2,3-Butanedione monoxime)	CAS: 57-71-6 EC: 200-348-5	0.58%	Acute Tox 4 (H302) Skin Sens 1 (H317)

* REACH registration numbers are not available for these substances as the annual tonnages do not require a registration or the registration is envisaged for a later registration deadline.

See section 16 for full description of R phrases and H statements.

SECTION 4: First Aid Measures

4.1 Description of first aid measures

EYE CONTACT: Wash thoroughly with water as a precaution.

INHALATION: Not considered an inhalation hazard.

SKIN CONTACT: Wash off with soap and water when conditions permit.

INGESTION: If swallowed, rinse mouth with water. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in Sections 2.2 and/or 11.

4.3 Indication of any immediate medical attention and special treatments needed

No specific treatment. Symptomatic treatment as required. First aiders should wear gloves.

SECTION 5: Firefighting Measures

5.1 Extinguishing media

Suitable extinguishing media: Use dry chemical, CO₂, water spray (fog) or foam

Not suitable extinguishing media: Water jet.

5.2 Special hazards arising from the substance or mixture

Decomposition products may include the following materials:

carbon dioxide
carbon monoxide
nitrogen oxides

5.3 Advice for fire fighters

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

SECTION 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Avoid breathing vapours, mist or gas. Put on appropriate personal protective equipment (see Section 8).

6.2 Environmental precautions

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and materials for containment and clearing up

Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see section 13). Dispose of in accordance with local regulations. Contaminated absorbent material may pose the same hazard as the spilled product.

6.4 References to other sections

See section 1 for emergency contact information and section 13 for waste disposal.

SECTION 7: Handling and Storage

7.1 Precautions for safe handling

Put on appropriate personal protective equipment (see Section 8). Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Avoid contact with eyes and mucous membranes. Empty containers retain product residue and can be hazardous.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Storage temperature should be between 15°C to 30°C. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food

and drink. Keep container tightly closed and sealed until ready for use. Use appropriate containment to avoid environmental contamination.

7.3 Specific end uses(s)

The full strength solution is applied on body surfaces after exposure to chemical warfare agents as described in Section 1.2. RSDL should not be used before exposure since its effectiveness following prophylactic use has not been evaluated. Generally, one 21 ml packet is sufficient to decontaminate hands, neck, and face. The packaging and sponge should be discarded after a single use, in compliance with all Federal, State/Provincial and local laws and regulations. Regulations may vary in different locations.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control parameters

Components with workplace control parameters:

RSDL contains no substances with occupational exposure control limit values in the EU.

UNITED STATES

Ingredient	Exposure Limits
Polyethylene Glycols	AIHA WEEL (United States, 2011). TWA: 10mg/m ³ 8 hour(s). Form Aerosol

CANADA

Occupational Exposure Limits		TWA (8hours)			STEL (15 mins)			Ceiling			
Ingredient	List Name	Ppm	Mg/m ³	Other	Ppm	Mg/m ³	Other	Ppm	Mg/m ³	Other	
Polyethylene Glycols	US AIHA 2011	—	10	—	—	—	—	—	—	—	—

Form: [a] Aerosol

8.2 Exposure controls

Engineering controls

General industrial hygiene practice. No special ventilation requirements.

Respiratory protection

Not required under normal conditions of use.

Hand/Skin Protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Eye protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Control of environmental exposure

Do not let product enter drains.

SECTION 9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Appearance:	Liquid [clear solution]
Colour:	Yellow. / Brown. / Orange
Odour:	No data available
Odour threshold:	No data available
pH:	10.35 to 10.85
Melting point:	0°C (freezing point)
Boiling point:	Decomposition temperature: > 200°C
Flashpoint:	Open cup: 238°C (460.4°F) [Cleveland.]
Evaporation rate:	0 (butyl acetate = 1)
Flammability:	No data available
Upper/lower flammability limits:	Upper: 6.9%, Lower: 1.1%
Vapour pressure:	< 0.0013 kPa (< 0.01 mm Hg) [20°C]
Vapour density:	> 1 [air = 1]
Relative density:	1.1
Solubility in water:	Soluble
Solubility in other solvents:	No data available
Partition coefficient (log K _{ow})	No data available
Auto-ignition temperature	No data available
Decomposition temperature	Decomposition temperature: > 200°C
Viscosity 40°C	Dynamic: 126 mPa•s (126 cP)
Explosive properties	No data available
Oxidising properties	No data available



9.2 Other information

No data available

SECTION 10: Stability and Reactivity

10.1 Reactivity

No data available.

10.2 Chemical stability

The product is stable.

10.3 Possibility of hazardous reactions

Under normal conditions of storage and use, hazardous reactions will not occur.

10.4 Conditions to avoid

The RSDL vehicle (methoxy polyethylene glycol [MPEG]) when combined with some commonly used decontamination materials, i.e., solid powdered HTH (calcium hypochlorite) or solid powdered Super Tropical Bleach, causes spontaneous combustion. Should RSDL be used on the same decontamination line as either of these products, care must be taken to keep them apart. Do not discard RSDL packaging and sponge into containers that contain or have contained HTH or Super Tropical Bleach.

10.5 Incompatible materials

Reactive or incompatible with the following materials: oxidizing materials, acids and alkalis

10.6 Hazardous decomposition products

Decomposition products may include the following materials: carbon dioxide, carbon monoxide, nitrogen oxides.

SECTION 11: Toxicological Information

11.1 Information on toxicological effects

Toxicokinetics

Product/ingredient name	Test	Species	Dose	Results
RSDL	Phase 1 PK topical application	Human	RSDL up to 84 ml for 24 hours. PK of DAM measured in blood/serum for up to 72 hours.	DAM is absorbed through human skin following RSDL topical application. Heat stress increased uptake. Washing to remove RSDL limited further uptake of DAM.

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
RSDL	LD50 Dermal	Rabbit	> Dermal 950 mg/kg	–
DAM	Dermal LD50	Rabbit	> 2000 mg/kg	

Chronic toxicity

Product/ingredient name	Result	Species	Dose	Exposure
KBDO	Chronic LD50 Dermal	Rat	1286 mg/kg	5 weeks

Skin corrosion/irritation

Product/ingredient name	Test	Species	Dose	Results
RSDL	21-Day cumulative (occluded) irritation study	Human	0.05mL on 1 cm sponge – topical application	RSDL significantly less irritating than SLS positive control significantly more irritating than saline negative control. Concluded that RSDL had a moderate potential for mild cumulative irritation in normal use.
RSDL	Evaluation of phototoxicity and photoallergy in humans	Human	0.05 mL on 1 cm diameter sponge applied paraspinal.	Under the conditions of the study there was no evidence of cutaneous RSDL phototoxicity or photoallergy

Serious eye damage/irritation

Product/ingredient name	Test	Species	Dose	Results
KBDO in MPEG	Ocular Installation	Rabbit	KBDO in 50:50 MPEG	Slight to moderate redness of the conjunctivae that was present 24-hours post dose. No treatment related microscopic findings. KBDO is not considered a risk for serious eye damage/irritation.

Respiratory/skin sensitisation

Product/ingredient name	Test	Species	Dose	Results
RSDL	Repeated insult patch test	Human	RSDL compared to 0.1% sodium lauryl sulphate and saline. RSDL applied neat (0.05 mL on 1 cm diameter sponge)	Under the conditions of the study RSDL was found to be non-sensitizing. Slight to mild erythema was frequently observed, 2 instances of moderate erythema and no observations of severe erythema.

Germ cell mutagenicity

Product/ingredient name	Test	Species	Dose	Results
RSDL	Bacterial Mutagenicity Assay	Salmonella typhimurium reverse mutation assay	RSDL – up to 5 mg/plate	Negative mutagenic response.
RSDL	In vivo mouse bone marrow micronucleus assay	Mouse	5F and 5M mice, 5 IP doses of RSDL up to 2000 mg/kg	Negative (non-genotoxic)

Carcinogenicity No data available. No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

Product/ingredient name	Test	Species	Dose	Results
RSDL	One generation reproduction study of RSDL in rats	Rats	Max dose 8mL/Kg/ Day dermal dose of RSDL for 8.5 weeks males and 2 weeks females	No adverse reproductive effects.

STOT-single exposure no data available

STOT-repeated exposure no data available

Aspiration hazard

Product/ingredient name	Test	Species	Dose	Results
RSDL	Viscosity and aspiration estimation	NA	NA	Not an aspiration hazard. RSDL has a kinematic velocity of 115 mm ² /s at 40°C

SECTION 12: Ecological Information**12.1 Toxicity**

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available. No known significant effects or critical hazards expected.

SECTION 13: Disposal Considerations**13.1 Waste treatment methods**

Do not dump into sewers, on the ground, or any body of water. All disposal practices must be in compliance with all Federal, State/ Provincial and local laws and regulations. Regulations may vary in different locations.

The Supplier and Manufacturer have no control on the management practices of parties handling or using this material. The information presented here pertains only to the product as shipped in its intended condition as described in section 3 of this SDS (Composition/ Information on ingredients).

Disposal should be in accordance with applicable regional, national and local laws and regulations.

Refer to Section 7 and Section 8 for additional handling information and protection of employees.



SECTION 14: Transport Information

	ADR	IMDG	ICAO
14.1 UN Number	—	—	—
14.2 UN Proper shipping name	Not dangerous goods	Not dangerous goods	Not dangerous goods
14.3 Transport hazard class(es)	—	—	—
14.4 Packing group	—	—	—
14.5 Environmental hazards	—	—	—
14.6 Special precautions for user	—	—	—
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	—	—	—

SECTION 15: Regulatory Information

This Safety Data Sheet is prepared in accordance with formatting described in the REACH Regulation (EC) No 1907/2006, and described in CLP Regulation (EC) No 1272/2008.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

No data available.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment is not required for this product and has not been carried out.

SECTION 16: Other Information

Revision information:

For external use only. Not for prophylactic use or whole body decontamination. Not a substitute for proper protective breathing devices and garments. Avoid unnecessary contact with eyes and mucous membrane. RSDL should not be used for wound decontamination because its effects on wounds and effects resulting from its absorption through the wound have not been studied.

Avoid extended contact with the skin. One of the ingredients (DAM) is absorbed through the skin. Studies with RSDL up to 84ml left on the skin for 24 hours showed minimal adverse effects.

RSDL should be used during pregnancy only when necessary; one of the ingredients: 2,3 butanedione monoxime (DAM) has been shown to cross the placental barrier in animal studies. (1) Animal reproduction studies have shown RSDL to be non-toxic for all of the reproductive parameters examined, including the neonates – RSDL is not teratogenic, not spermicidal, and not embryocidal. (2) No human studies on pregnant women have been conducted.

1. Passage of Tertiary and Quaternary Nitrogen Compounds Through the Rat Placenta; Arch Int Pharmacodyn Ther. 1974 Aug 210 (2):232-240.

2. One-Generation Reproduction Study of RSDL in Rat; Southern Research Study Number: 9200.05.01 February 13, 2003. Southern Research Institute, Birmingham Alabama

List of Abbreviations used in this SDS:

ADR	International Carriage of Dangerous Goods by Road
AIHA	American Industrial Hygiene Association
CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging Regulation (EC) no 1272/2008
DSD	Dangerous Substances Directive 67/548/EEC
DPD	Dangerous Preparations Directive 1999/45/EC
EC	European Community/Commission
IBC	International Bulk Chemical
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
MARPOL	Maritime Pollution
MG/M ³	Milligram per Cubic Meter
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) no 1907/2006
TWA	Time Weighted Average
UN	United Nations
vPvB	very Persistent, very Bioaccumulative
WEEL	Workplace Environmental Exposure Limit

Method used for classification of mixtures:

Human and rabbit test data

P and H Statements used in Sections 2 and 3

P280	Wear protective gloves/protective clothing/eye protection/face protection
H302	Harmful if swallowed
H317	May cause an allergic skin reaction